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(54) Intramuscular electrode for neuromuscular stimulation system

Intramuskuläre Elektrode für ein neuromuskuläres Reizungssystem

Electrode intramusculaire pour système de stimulation neuromusculaire

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- **IEEE ENGINEERING IN MEDICINE & BIOLOGY SOCIETY 11TH ANNUAL INTERNATIONAL CONFERENCE, vol. 11, 9th November 1989, pages 1520-1521; W.D. MEMBERG et al.: "A surgically-implanted intramuscular electrode for an implantable neuromuscular stimulation system"**

EP 0 408 358 B2

Description

[0001] The present invention relates to implantable electrodes. It finds particular application in conjunction with functional neuromuscular stimulation systems and will be described with particular reference thereto.

[0002] The electrodes of neuromuscular stimulation systems are commonly implanted in the muscles of a patient's arms or legs. Generally, these electrodes are different from electrodes implanted in a patient's heart in conjunction with pacemakers to accommodate the differences in the muscular tissue and the manner and frequency with which the muscular tissue contracts. An example of an electrode for implantation in the heart is shown in U.S. Patent No. (US-A)4,282,885 (Bisping).

[0003] One type of neuromuscular stimulation electrode includes a length of insulated wire in which the terminal one to one and a half centimetres has been stripped to expose the electrical conductor. The electrical conductor is folded back in a sharp V to form a barb. This exposed end and the immediately contiguous lead wire are inserted into a hollow bore in the cannula of a syringe-like tool and "injected" into the muscle tissue. The barb defined by folding the exposed conductor back on itself inhibits the electrode from being extracted. One of the primary drawbacks to electrodes of this type is fatigue failure of the electrical conductor.

[0004] Various electrode designs have been developed that improve upon the stripped end lead electrode. One improved electrode configuration is described in "Electrical Activation of Respiratory Muscles by Methods Other than Phrenic Nerve Cuff Electrodes", Peterson, Stellato, Nochomovitz, Dimarco, Abelson, and Mortimer, PACE, Vol. 12, pp. 854-860, May 1989, which publication is based on a paper presented at the Diaphragm Stimulation Symposium at Cardiostim '88, June 15-18, 1988. In this electrode, two "Teflon" (Regd. Trade Mark) coated multistrand stainless steel wires were wrapped in a double helical pattern. At the terminal end, about the last half centimetre of the "Teflon" coating of the helically wrapped conductors was removed. The bare stainless steel multistrand conductors were wrapped with the same helical pattern. A colored polypropylene core was threaded through the helix and another millimetre or so beyond the end of the bare wires. A plurality of lengths of polypropylene about a half centimetre long were bundled around the exposed end of the polypropylene core. The core and the surrounding elements were inserted about a millimetre into a conforming metal tube which was heated, e.g. with a soldering iron, until the polypropylene filaments fused to the polypropylene core as barbs at the terminal end. Once injected into the muscle, muscle tissue would grow around the exposed wire coil and the polypropylene barbs anchoring it securely.

[0005] Although successful, this electrode does have drawbacks. First, fusing the plurality of polypropylene barbs to the core is difficult and labour intensive. Second, the reduction in diameter at the end of the insulation where the stripped helix of electrical conductor begins is a natural failure point. Flexing movement is focused at this point during muscular movement, eventually leading to stress failures.

[0006] The preamble of claim 1 is shown in US-A-3 788 329 when read together with US-A-3 572 344.

[0007] The present invention contemplates a new and improved electrode and its method of construction which overcomes or at least greatly mitigates the above referenced problems and others. The present invention is defined in Claim 1 herein.

[0008] One advantage of the present invention as described and illustrated herein is that it anchors securely into muscle tissue.

[0009] Other advantages are resistance to stress failures of the electrical conductor, and that construction is simplified.

[0010] The invention may take physical form in various parts and arrangements of parts or in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention. The figures are illustrative of a method of constructing and inserting an electrode in accordance with the present invention and the resultant electrode. In the accompanying drawings:-

FIGURE 1A is a hollow core, double helical configuration of insulated multi-strand electrode lead;

FIGURE 1B illustrates the hollow core, double helical configuration encased in Silastic sheathing with de-insulated ends of the electrode lead wrapped around the sheathing with a polypropylene anchor ready for insertion;

FIGURE 1C is illustrative of the Silastic sheath coil, electrode end of FIGURE 1C, in partial section, with the anchor inserted;

FIGURE 1D is the assembly of FIGURE 1C with the anchor fused to the helical electrode lead;

FIGURE 2A is a probe for determining a point of insertion;

FIGURE 2B illustrates sliding a metal sheath or canula over the probe and withdrawing the probe;

FIGURE 2C illustrates inserting the electrode and a carrier into the metal sheath or canula after the probe has been removed;

FIGURE 2D shows the electrode inserted at the determined point of insertion;

FIGURE 2E illustrates removal of the carrier from the canula; and,

FIGURE 2F illustrates removal of the canula from the implanted electrode.

[0011] With reference to FIGURE 1A, a helix **10** is defined by a pair of electrical conductors **12a, 12b** wound into an open core, double helical configuration. Each electrical conductor is selected to have a relatively low electrical resistance, high mechanical strength, high

ductility, high fatigue resistance, and high corrosion resistance. The preferred conductors for multistrand wire 14a, 14b include Type 316 stainless steel, platinum alloys, such as platinum iridium, nickel cobalt chromium molybdenum alloys, and iron nickel cobalt chromium molybdenum alloys. The conductors are preferably seven strand wires arranged such that the strands pack in a hexagonal close packed pattern for optimum compactness. The wire strands are wound such that they have a pitch angle 16 of about 17° relative to a plane transverse to the cable axis in order to optimize tensile and compressive forces. In order to reduce electrical conductivity and increase redundancy, a third or additional conductor may be wound in the helix. However, the physical size of one or more additional conductors may necessitate increasing the pitch angle and reducing tensile or compressive strength.

[0012] The conductors **12a,b** are insulated with a biologically inactive coating **18a**, **18b** which has a high tensile strength and ductility, such as TEFLON (Trade Mark), polyurethane, or silicon rubber. Optionally, the strength of the cable may be improved by winding the electrical conductors around a multistrand polymeric core, such as polypropylene. However, in the preferred embodiment, the helix has an open core **20** to increase the flexibility and fatigue resistance of the electrical conductors. Further, the conductors are wound with a gap **22** between adjacent windings to accommodate compressive, tensile, and bending stresses.

[0013] With reference to FIGURE 1B, the open core helix **10** is encased in a silicon rubber sheath 30 e.g. of "Silastic" material. In the preferred embodiment, the sheathing 30 is an open core tube within which the helix **10** is received. The sheath is preferably shrunk into firm frictional engagement with the helix. The sheathing **30** encloses the helix which prevents tissue around an implanted lead from growing into the helix. This reduces anchoring of the lead to the tissue and permits limited movement between the tissue and the lead.

[0014] At a terminal or implanted end **32** of the sheathing **30**, the TEFLON™ insulation **18a,b** is removed and the de-insulated wire filaments **14a,b** are wrapped around the exterior periphery of the silastic sheathing to define an electrically conductive surface **34** that conducts charge to surrounding tissue. The ends of the electrical conductors are fastened, such as by insertion through a segment of the sheathing **30** and sealing with silicon adhesive **36**.

[0015] The length of the de-insulated wire is selected to provide a surface area **34** that delivers a charge density per stimulus pulse that is high enough to depolarize a nerve, but low enough to avoid tissue damage and electrode corrosion. This surface area is selected in accordance with the stimulus pulses to be applied and the nerve tissue to be stimulated. It will be noted that by de-insulating the electrical conductor and using the conductor itself as the electrode eliminates welds or other electrical junctions which could be subject to galvanic corrosion are avoided. Moreover, the diameter of the electrical lead windings is commensurate with the diameter of the tubing 30, thus avoiding a diameter reduction or other point at which stresses are focused and stress failures become most apt to occur. The slight compression of the sheathing as the wire is wrapped renders the diameter of the conductive surface **34** substantially the same as the diameter of the uncompressed sheath diameter. Of course, for some applications or to facilitate production efficiency, it may be advantageous to connect the electrical leads with a separate metal element which at least in part surrounds the implanted end **32** of the sheathing.

[0016] A separate anchor **40** has a thermoplastic, polymeric shaft **42** of an appropriate diameter to be received in the hollow core **20** of the helix **10**. The shaft portion and a plurality of tines **44** are anchored together in an anchor head portion **46**. Preferably, the entire anchor is constructed of a polymeric material rather than a metal to avoid potential corrosion sites. Polypropylene is preferred as the polymeric anchor due to its ready availability in monofilament form and its biocompatibility. The monofilament polypropylene tines function as barbs to anchor the electrode securely, particularly while the muscle tissue is growing into firmer attachment with the electrode. However, the polymeric tines are also sufficiently flexible that the electrode can be removed surgically without the tissue damage associated with metal or rigid tines.

[0017] With reference to FIGURE 1C, the polymeric shaft **42** is inserted into the hollow core **20** of the leads **12a,b** of the helix. The polymeric shaft is constructed of a thermoplastic with a lower softening point than the sheathing **30** or the insulation **18a,b**. The terminal end of the electrode is heated such that the shaft softens and flows into gaps **22** in the helix **10** as illustrated in FIGURE 1D. This flow anchors the shaft, hence the anchor to the electrode conductors **12a,b**, rendering them substantially inseparable. Moreover, the polymeric flow tends to seal the terminal end of the sheathing, limiting fluid permeability. Optionally, additional sealants may be added to inhibit biological fluids from flowing into the sheathing after the electrode is implanted.

[0018] The completed electrode is implanted into a selected point within the patient's muscle tissue. With reference to FIGURE 2A, a probe **50** that includes an inner conductive rod **52** that is covered with insulation **54**, except at its two ends. During surgery, an incision is made into the skin and the probe is inserted therethrough into the muscle. A source of stimulus current **56** is selectively connected with the probe to induce a contractile response in the muscle. The probe is moved or repositioned until a desired contractile response is achieved.

[0019] With reference to FIGURE 2B, a metal sheath **58** is placed over the probe. The metal sheath is stainless steel tubing that has longitudinal slots cut into one end. The end of the metal sheath is positioned adjacent

the end of the probe and the probe is withdrawn. With reference to FIGURE 2C, the electrode is placed in a lead carrier **60**, such as half circular length of tubing which is dimensioned to be slidingly received in the metal sheath **58** and to receive the lead therein. The anchor is inserted into the metal sheath followed by the lead carrier and the remainder of the lead. The lead carrier advances the lead until the electrically conductive surface **34** is at the same position as the tip of the probe (FIGURE 2D). A depth of insertion gauging means **62** is provided for determining when the electrically conductive surface is in the same position relative to the inserted end of the metal sheath as was the probe. In the preferred embodiment, the depth of insertion gauging means includes a plurality of slots **64** in the metal sheath and a plurality of tabs **66** on the carrier. The slots and tabs are fashioned a coordinated length from the inserted ends of the metal sheath and carrier such that the electrically conductive surface **34** of the electrode is properly positioned.

[0020] With reference to FIGURE 2E, the carrier is removed from the metal sheath. Referring to FIGURE 2F, the metal sheath is slid longitudinally off the lead, relying on the anchor **40** to hold the lead at the selected location in the muscle tissue both during removal of the sheath and thereafter.

[0021] The invention has been described with reference to the preferred embodiment. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the claims of this invention be construed in accordance with EPC Article 69 and its Protocol.

Claims

1. An electrode for surgical implantation the electrode comprising:

   a helix (10) of electrical conductor (12a, 12b); and
   a sheath (30) which surrounds and encases the helix and is flexible and insulating;
   wherein an exposed portion of the electrical conductor (12a, 12b) is wrapped around a periphery of a terminal end of the sheath (30) to form an electrical contact for transmitting electrical energy to tissue surrounding the implanted electrode;
   characterised in that;

   (i) the helix (10) has a hollow core (20);
   (ii) an anchor (40) is provided for anchoring the electrode to tissue within which it is implanted, the anchor having a shaft (42) of thermoplastic material which is received in the hollow core (20) at a terminal end of the electrode; and
   (iii) the shaft (42) has been heated to flow into conformity with the helix (10).

2. The electrode according to claim 1 wherein the electrical conductor (12a, 12b) is a multistrand wire that, apart from the exposed portion, is encased in insulation.

3. The electrode according to claim 2 wherein the electrical conductor (12a, 12b) includes two multifilament wires, each encased in insulation and disposed side by side in the helix.

4. The electrode according to any preceding claim wherein gaps are provided between adjacent loops of the electrical conductor (12a, 12b).

5. The electrode according to any preceding claim wherein the anchor includes a plurality of polymeric barbs (44), the barbs being sufficiently strong to anchor the electrode into the tissue within which it is transplanted and sufficiently resilient so as to yield and permit extraction of the electrode without ripping the tissue.

6. The electrode according to claim 5 wherein the anchor barbs and shaft are constructed of polypropylene.

7. A method of constructing an electrode comprising:

   fashioning a helix (10) of insulated electrical conductor (12a,b);
   sheathing the helix with material (30);
   the sheathing material being flexible and insulating; and
   wrapping, at the terminal end of the sheathing, an exposed end (34) of the electrical conductor around a periphery of the sheathing adjacent the terminal end thereof;
   characterised by:

   (i) inserting a thermoplastic shaft (42) of an anchor (40) into an open core of the helix adjacent the terminal end of the sheathing; and

   (ii) thermally deforming the thermoplastic shaft (42) into locking engagement with the helix (10).

Patentansprüche

1. Elektrode für die chirurgische Implantation, wobei die Elektrode umfaßt:

   eine Spirale (10) eines elektrischen Leiters (12a, 12b) und eine Umhüllung (30), die die Spirale umgibt und ummantelt und flexibel und

isolierend ist,
wobei ein freiliegender Abschnitt des elektrischen Leiters (12a, 12b) um den Umfang eines Endes der Umhüllung (30) gewickelt ist, um einen elektrischen Kontakt zur Übertragung von elektrischer Energie auf das die implantierte Elektrode umgebende Gewebe zu bilden, dadurch gekennzeichnet, daß:

(i) die Spirale (10) einen hohlen Kern (20) hat,
(ii) ein Anker (40) vorgesehen ist, um die Elektrode an dem Gewebe zu verankern, in dem sie implantiert ist, wobei der Anker einen Stiel (42) aus thermoplastischem Material hat, der im hohlen Kern (20) am Ende der Elektrode aufgenommen wird, und
(iii) der Stiel (42) so erhitzt wurde, daß er in Übereinstimmung mit der Spirale (10) fließt.

2. Elektrode nach Anspruch 1, wobei der elektrische Leiter (12a, 12b) ein mehrsträngiger Draht ist, der abgesehen von dem freiliegenden Abschnitt von einer Isolierung umhüllt ist.

3. Elektrode nach Anspruch 2, wobei der elektrische Leiter (12a, 12b) zwei mehrfädige Drähte einschließt, die beide von einer Isolierung umhüllt sind und nebeneinander in der Spirale angeordnet sind.

4. Elektrode nach einem der vorstehenden Ansprüche, wobei zwischen benachbarten Schleifen des elektrischen Leiters (12a, 12b) Zwischenräume vorgesehen sind.

5. Elektrode nach einem der vorstehenden Ansprüche, wobei der Anker mehrere Polymerwiderhaken (44) einschließt, wobei die Widerhaken genügend fest sind, um die Elektrode in dem Gewebe zu verankern, in das sie implantiert ist, und genügend elastisch sind, um ein Herausziehen der Elektrode ohne Zerreißen des Gewebes zu erreichen und zu ermöglichen.

6. Elektrode nach Anspruch 5, wobei die Ankerwiderhaken und der Stiel aus Polypropylen aufgebaut sind.

7. Verfahren zur Herstellung einer Elektrode, welches umfaßt:

Anpassen einer Spirale (10) eines isolierten elektrischen Leiters (12a, b),
Umhüllen der Spirale mit einem Material (30), wobei das Umhüllungsmaterial flexibel und isolierend ist, und
Wickeln eines freiliegenden Endes (34) des elektrischen Leiters am Ende der Umhüllung um den Umfang der Umhüllung neben deren Ende,
gekennzeichnet durch:

(i) das Einsetzen des thermoplastischen Stiels (42) eines Ankers (40) in den offenen Kern der Spirale neben dem Ende der Umhüllung und
(ii) das thermische Verformen des thermoplastischen Stiels (42) in einen verankernden Eingriff in die Spirale (10).

Revendications

1. Electrode pour implantation chirurgicale, l'électrode comportant :

une hélice (10) d'un conducteur électrique (12a, 12b) ; et
une gaine (30) qui entoure et renferme l'hélice et qui est souple et isolante ;
dans laquelle une portion exposée du conducteur électrique (12a, 12b) est enroulée autour d'une périphérie d'une extrémité terminale de la gaine (30) pour former un contact électrique afin de transmettre de l'énergie électrique à un tissu entourant l'électrode implantée ;
caractérisée en ce que :

(i) l'hélice (10) comporte un coeur creux (20) ;
(ii) un ancrage (40) est prévu pour ancrer l'électrode au tissu dans lequel elle est implantée, l'ancrage ayant une tige (42) de matière thermoplastique qui est reçue dans le coeur creux (20) à une extrémité terminale de l'électrode ; et
(iii) la tige (42) a été chauffée pour épouser, en coulant, la forme de l'hélice (10).

2. Electrode selon la revendication 1, dans laquelle le conducteur électrique (12a, 12b) est un fil à brins multiples qui, en dehors de la portion exposée, est enfermé dans un isolant.

3. Electrode selon la revendication 2, dans laquelle le conducteur électrique (12a, 12b) comprend deux fils à filaments multiples, renfermés chacun dans un isolant et disposés côte à côte en hélice.

4. Electrode selon l'une quelconque des revendications précédentes, dans laquelle des espaces sont prévus entre des boucles adjacentes du conducteur électrique (12a, 12b).

5. Electrode selon l'une quelconque des revendica-

tions précédentes, dans laquelle l'ancrage comprend une pluralité de barbes de polymère (44), les barbes étant suffisamment solides pour ancrer l'électrode dans le tissu dans lequel elle est implantée et suffisamment élastiques pour fléchir et permettre une extraction de l'électrode sans déchirer le tissu.

6. Electrode selon la revendication 5, dans laquelle les barbes d'ancrage et la tige sont constituées de polypropylène.

7. Procédé de construction d'une électrode comprenant :

le façonnage d'une hélice (10) en un conducteur électrique isolé (12a, 12b) ;
le gainage de l'hélice avec une matière (30), la matière de gainage étant souple et isolante ; et
l'enroulement, à l'extrémité terminale du gainage, d'une extrémité exposée (34) du conducteur électrique autour d'une périphérie du gainage adjacente à son extrémité terminale ;
caractérisé par :

(i) l'insertion d'une tige thermoplastique (42) d'ancrage (40) dans un coeur ouvert de l'hélice à proximité immédiate de l'extrémité terminale du gainage ; et
(ii) la déformation thermique de la tige thermoplastique (42) en prise d'accrochage avec l'hélice (10).

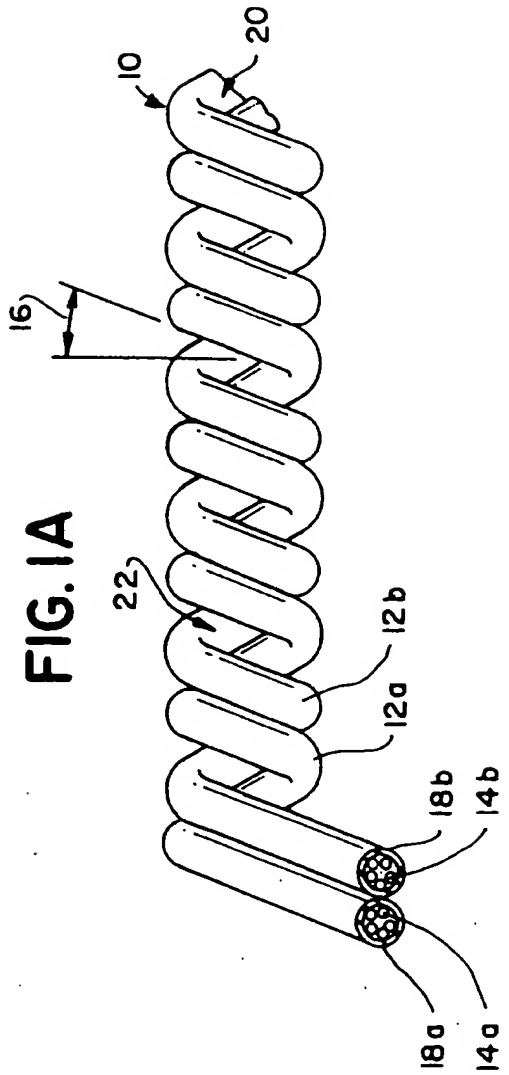
10
20
16
22
12b
12a
18b
14b
18a
14a

FIG. 1A

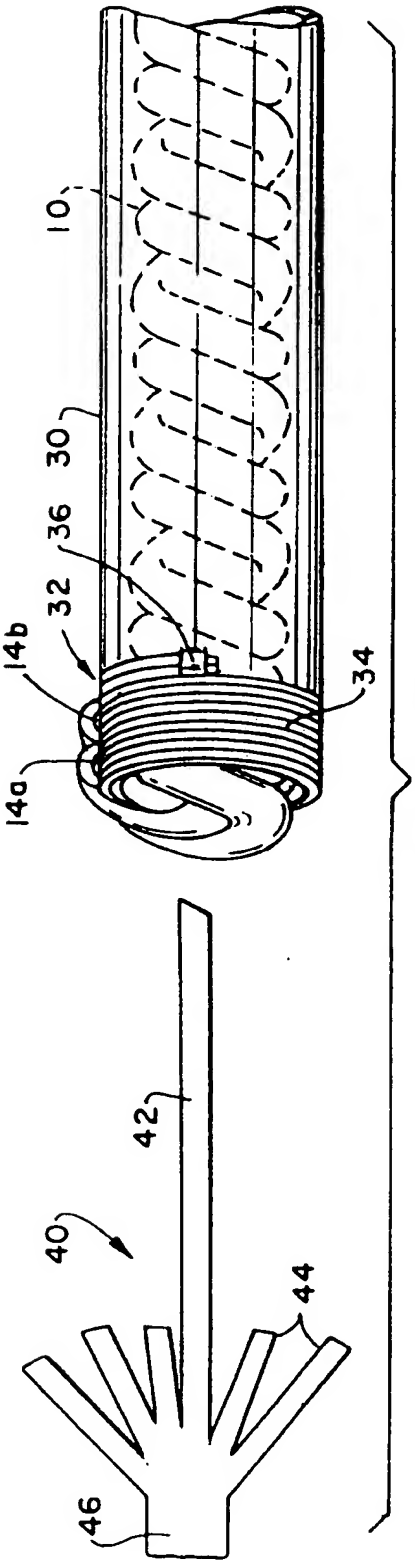
10
30
36
32
14b
14a
34
42
40
44
46

FIG. 1B

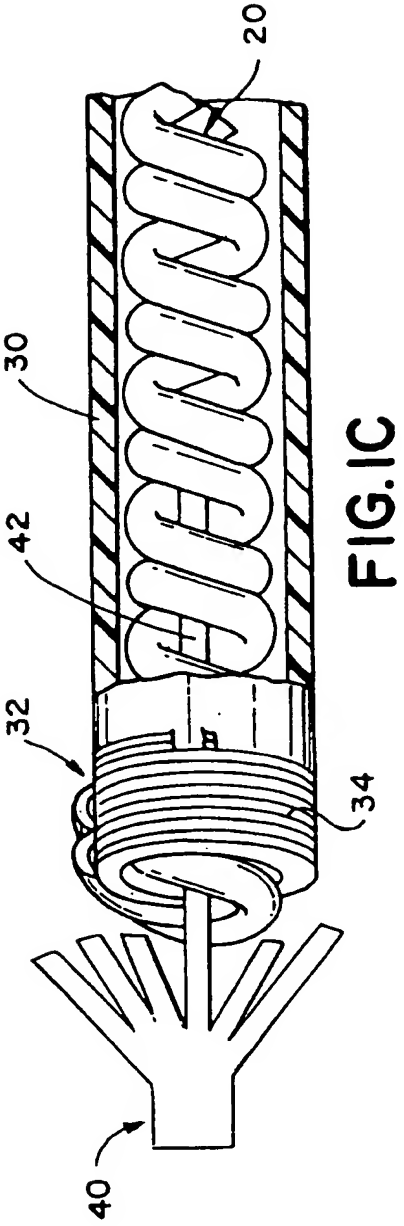

FIG.IC

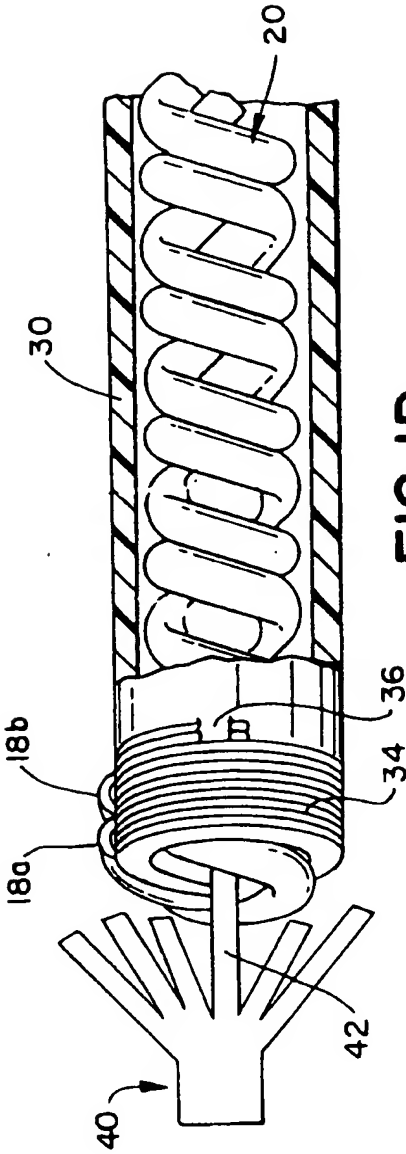

FIG.ID

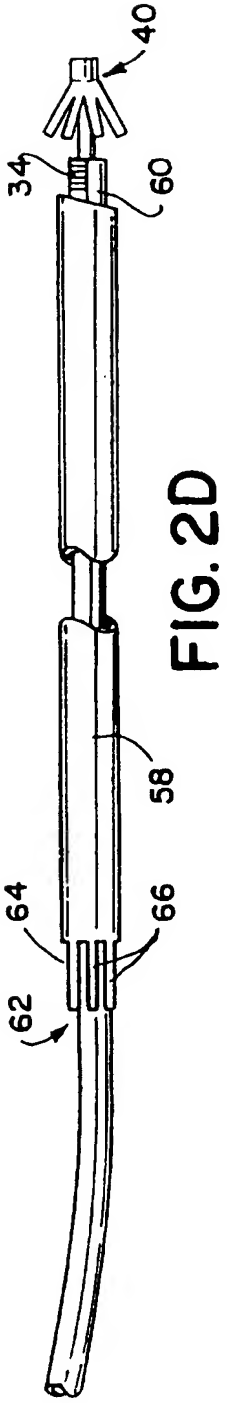

FIG. 2D

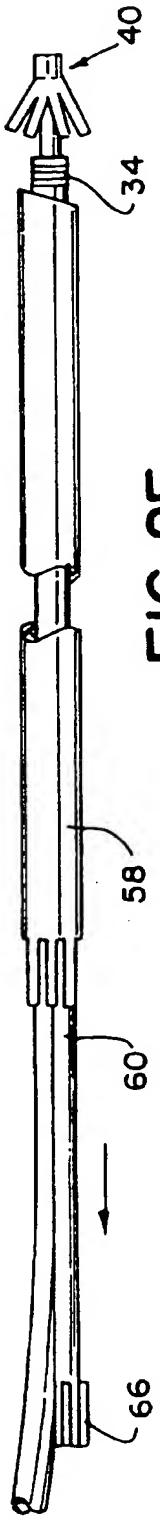

FIG. 2E

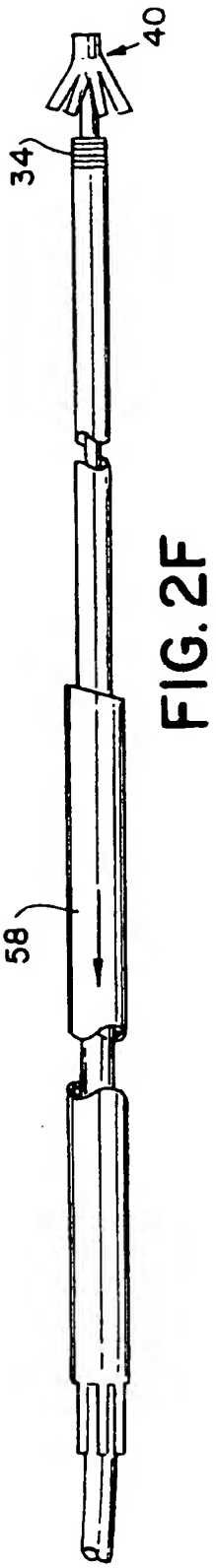

FIG. 2F

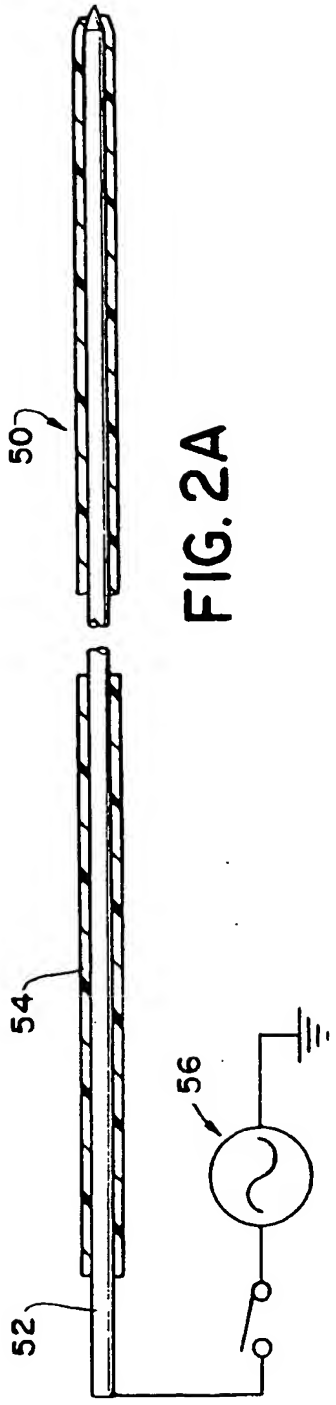

FIG. 2A

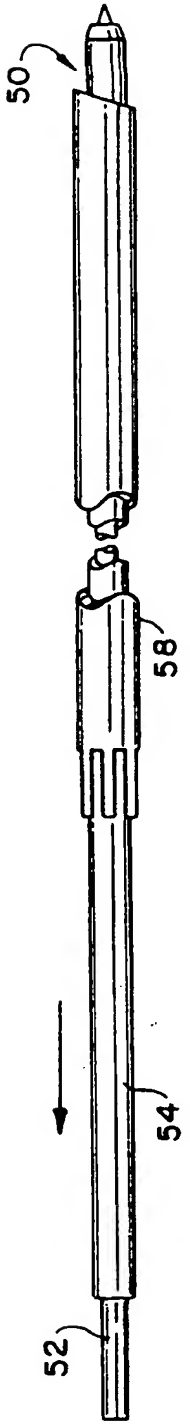

FIG. 2B

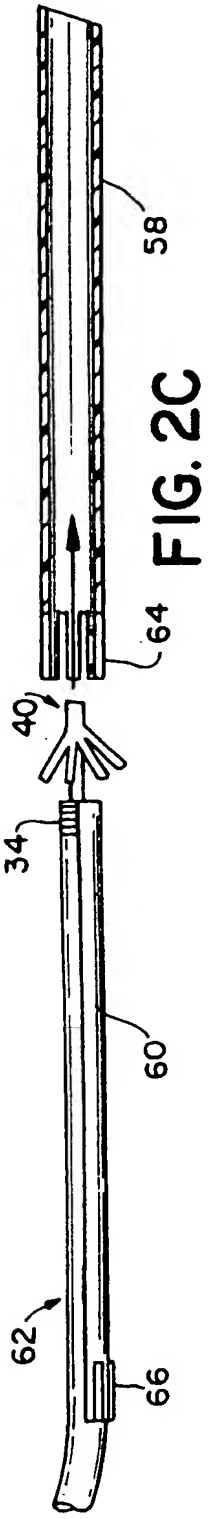

FIG. 2C